Claims **3, 5-8, 10, 13-42 and 44-50** were previously cancelled, no additional claims have been cancelled, claims **1 and 9** have been further amended, and no new claims have been added as per the amendment filed April 25, 2008. No additional Information Disclosure Statements (IDSs) have been received as of the mailing date of this Office action. A declaration signed by Mssr. Robert J. Sarama filed April 25, 2008 has also been received and reviewed during the preparation of this Office action.

Claims **1-2, 4, 9, 11-12 and 43** remain in the case.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-2, 4, 9, 11-12 and 43** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Nutramax Laboratories '816** (PTO-1449 ref. **CA**) in view of **Florio '715** (PTO-1449 ref. **BF**), **Martino '692** (PTO-1449 ref. **BM**), **Burger '919** (PTO-14549 ref. **BG**), **Murad '594** (PTO-1449 ref. **BE**), and **Herschler '878** (PTO-1449 ref. **AU**) and further in view of **applicant's own admissions**, **Vanderveen et al.** (PTO-892 ref. **U**) and **Swinyard et al.** (PTO-892 ref. **V**).

The instant claims are directed to beverage (liquid) compositions containing cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine and numerous additional nutritional and non-nutritional additional ingredients and carriers for the purpose of treating arthritis, and a kit for this specific purpose including written instructions for the administration/consumption of the composition to, or by, an end user in need thereof.

Nutramax Laboratories '816 (PTO-1449 ref. **CA**) discloses the administration of compositions including glucosamine, chondroitin, and optionally various vitamins and minerals (nutrients) for the treatment of arthritis in mammals.

Florio '715 (PTO-1449 ref. **BF**) discloses the administration of compositions including glucosamine, chondroitin, and optionally lipids/fatty acids in liquid form including administration instructions for the treatment of arthritis in mammals.

Marino '692 (PTO-1449 ref. **BM**) discloses the administration of compositions including cartilage, glucosamine, chondroitin, and optionally various nutrients for the treatment of arthritis in mammals.

Burger '919 (PTO-1449 ref. **BG**) also specifically cited by applicant's disclosure) discloses the administration of compositions including glucosamine, and optionally lipids/fatty acids for the treatment of arthritis in mammals.

Murad '594 (PTO-1449 ref. **BE**) discloses the administration of compositions including glucosamine, chondroitin, and optionally nutrients including vitamins and minerals for the treatment of arthritis in mammals.

Herschler '878 (PTO-1449 ref. **AU**) discloses the administration of compositions including methylsulfonylmethane, and optionally as part of a nutrient (food) for the treatment of arthritis in mammals.

Applicant's own admissions at page 1, original lines 12-13, applicant admits that the prior art teaches the effectiveness of glucosamine and chondroitin in the treatment of osteoarthritis (hereinafter "arthritis"). Applicant also admits in the same paragraph that numerous commercial products in this art area are readily formulated into beverage compositions immediately prior to consumption. At the top of page 2, applicant further admits that "[c]hondoprotective agents may be delivered in the form of compositions having high sugar content." Applicant also admits at page 11, last full paragraph, that methylsulfonylmethane is known in the prior art to have been administered to treat arthritis. Applicant admits at page 12, three lines from the bottom of the page, that "[s]weetening agents are commonly known in the art," and at lines 9-11 of page 12 also admits that certain naturally occurring sweeteners are well known in that art. At the top of page 14, applicant also admits that other commercially available sweeteners including "saccharin" are well known in the art.

Vanderveen et al. (PTO-892 ref. **U**) in chapter 51 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Vitamins and Other Nutrients," discloses a long list of

substances normally found in food stuffs including the nutrients "glucose," "fats and oils," and "fructose."

Swinyard et al. (PTO-892 ref. **V**) in chapter 66 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Pharmaceutical Necessities," discloses numerous substances included within the instant claims including generically "flavoring agents" including "saccharin," "cherry juice," "raspberry juice," and "sucrose," "Vehicles" and "Diluting Agents" including water, "Emulsifying and Suspending Agents," "Pharmaceutical Solvents" including "water," and "Miscellaneous Pharmaceutical Necessities" including "lactose."

Applicant's disclosure does not provide any showing of unexpected results. Therefore, applicant has merely provided directions for the admixing of active ingredients of known pharmaceutical activity (cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine) each of which has been included in one or more of the cited prior art compositions which are asserted repeatedly in the prior art to be effective in the treatment of arthritis. These pharmaceutical activities are each also admitted by applicant's own disclosure. The additional components of the claimed composition are also well known in the art and are not asserted to be anything other than carriers or pharmaceutical necessities and/or nutrients several of which are specifically listed in the cited art, and none of which are asserted by applicant to represent a critical feature for any final composition. The presence of instructions directed to the end user is also a feature known in the prior art cited above (see ref. **BF**).

In light of applicant's failure to provide any data to support an unexpected benefit from the instant claimed compositions, the instant claimed compositions, kits thereof and methods of administration thereof, are deemed to lack patentable distinction as being nothing more than a mixture of substances known in the prior art as anti-arthritis agents and therefore obvious compositions to be administered to a host in need thereof. Any additional compounds acting in concert has the carrier or excipient (e.g. sweeteners, etc., etc.) have been included in the spirit of making the resultant composition palatable and optionally nutritious as admitted by applicant's own disclosure, and as generically taught by the Vanderveen and Swinyard disclosures.

Therefore, the instant claimed compositions and kits with instructions and methods of administration would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed April 25, 2008 have been fully considered but they are not persuasive.

Examiner has carefully read the declaration filed under 37 C.F.R. §1.132 and signed by Mssr. Sarama. The declaration discloses that an increase in the proportion of erythritol appears to protect the color stability of the product from the deleterious effects of added iron. The declaration does not report on the effect of removal of high fructose corn syrup from the original formulation on the color stability of the formulation.

The declaration discloses that applicant has determined one possible partial explanation for the change in color stability, but has not provided either a comprehensive explanation for the change in color stability or an analysis of both possible causes of this change.

An the declaration does not appear to provide any showing that there are any unexpected results following the re-formulation of the tested product, or the amendment of said re-formulation. It appears that Mssr. Sarama and associates have conducted nothing more or less than routine experimentation of a kind to be expected when decisions are made to re-formulate a product, including in this case how to amend the re-formulation to minimize problems with color/product stability when a heat stress is applied.

Therefore, the above rejection is deemed to remain valid and has therefore been maintained.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-**

0651. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
06/22/2008

/Lawrence E. Crane/

Patent Examiner, Art Unit 1623

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